

Exhibit A



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FDA FREEDOM OF INFORMATION ACT REQUEST

VIA ONLINE PORTAL

June 1, 2022

Food and Drug Administration
Division of Freedom of Information
Office of the Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: de Garay Request for FDA Emails (*IR#06111*)

Dear Sir or Madam:

This firm represents Patrick and Stephanie de Garay, parents of [REDACTED] de Garay. On behalf of our clients, please provide the following records to foia@sirillp.com in electronic form:

Each and every email communication between December 30, 2020 and the date of search sent or received by Janet Woodcock, Stephen Hahn, Peter Marks, Marion Gruber, Philip Krause, Paul Richards, and/or Lorrie McNeill that includes the words (“[REDACTED]” or “[REDACTED]”) and (“deGaray” or “de Garay”) in the body, subject line, or any other part of the email.

See attached declaration and corresponding documents regarding the waiver of privacy rights and consent to release responsive records. (Exhibit 1.)

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. Our clients reserve all rights to appeal the withholding or deletion of any information.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and our clients may immediately take further action.

Furthermore, we specifically request that the agency provide us with an estimated date of completion for this request.

If you would like to discuss our request or any issues raised in this letter, please feel free to contact us at (212) 532-1091 or foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

/s/ Aaron Siri

Aaron Siri, Esq.

Elizabeth A. Brehm, Esq.

Colin M. Farnsworth Esq.

Exhibit 1

DECLARATION OF PATRICK DE GARAY

STATE OF OHIO

COUNTY OF CLERMONT

I, Patrick de Garay, being duly sworn on oath do say;

1. I am the legal guardian of [REDACTED] de Garay who was born on [REDACTED]. **Exhibit A – [REDACTED] de Garay’s Birth Certificate**
2. [REDACTED] was a participant in Pfizer’s COVID-19 vaccine clinical trial for 12- to 15-year-olds. **Exhibit B – Proof of [REDACTED] de Garay’s Trial Participation**
3. I have retained legal counsel, Siri & Glimstad LLP (“Attorney”), to facilitate the filing, processing, and production of records requests concerning my daughter [REDACTED] de Garay from the files of any federal health authority, including Health and Human Services (“HHS”), National Institutes of Health (“NIH”), Food and Drug Administration (“FDA”), and Center for Disease Control and Prevention (“CDC”) pursuant the Freedom of Information Act (“FOIA”) (5 U.S.C. § 552, as amended).
4. I invoke all the privileges and rights I have as the legal guardian of [REDACTED] de Garay to obtain the information requested by my Attorney.
5. I authorize the release of records pertaining to a minor: I waive any and all privacy rights afforded to me and [REDACTED] de Garay that may be implicated by FOIA requests sent by my Attorney, and I consent to the release of all responsive records to my Attorney.
6. I am willing and able to sign any additional forms necessary to authorize the release of records responsive to my Attorney’s FOIA requests.

Attachments:

Exhibit A – [REDACTED] de Garay's Birth Certificate

Exhibit B – Proof of [REDACTED] de Garay's Trial Participation

Signed 11 day of May 2022

Patrick de Garay
Signature of Patrick de Garay

I, Thomas R Campbell Notary public for the state of
Ohio witnessed said Patrick de Garay sign
the above statement this 11 day of May 2022.

Notary Public for [Signature]

1 of 1

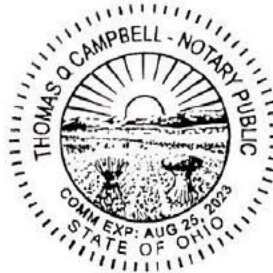


Exhibit A

WARNING: IT IS ILLEGAL TO DUPLICATE THIS COPY BY PHOTOSTAT OR PHOTOGRAPH.

DATE
ISSUED **May 29, 2008**

SEX FEMALE

PATRICK KEVIN DE GARAY

MOTHER'S MAIDEN NAME

STEPHANIE CATHARINE HOOK



enjoy

Frank Zerofoli

Frank Yeropoli
State Registrar



H105 105 1VV Rev 06/06

THE DOCUMENT FACE CONTAINS A YELLOW BACKGROUND AND EMBOSSED SEAL.
THE BACK CONTAINS SPECIAL LINES WITH TEXT.

WARNING: THIS DOCUMENT IS PRINTED ON SECURITY WATERMARKED PAPER
DO NOT ACCEPT WITHOUT VERIFYING THE PRESENCE OF THE WATERMARK.

9621522

The information appearing on the certified copy of birth is exactly transcribed from information contained on the original birth certificate as filed with the Division of Vital Records.

If you wish to correct the certified copy issued, please complete the lower portion of this form in the presence of a notarizing official.

Mail completed form to: Division of Vital Records
101 South Mercer Street
P.O. Box 1528
New Castle, PA 16101

PLEASE SUBMIT DOCUMENTARY EVIDENCE TO SUPPORT THE CHANGES REQUESTED SUCH AS A COPY OF A BAPTISMAL RECORD, EARLY SCHOOL RECORD, MILITARY RECORD, INSURANCE POLICY OR MARRIAGE LICENSE.



DATA	ORIGINAL RECORD NOW READS	CORRECTIONS DESIRED (print full names, dates, other)
NAME AT BIRTH		
DATE OF BIRTH		
SEX		
OTHER ERROR		
OTHER ERROR		
S E A L	SUBSCRIBED AND SWORN TO BEFORE ME: MO. DAY YEAR	FATHER'S SIGNATURE
	SIGNATURE OF PERSON ADMINISTERING OATH	MOTHER'S SIGNATURE
		SUBJECT'S SIGNATURE
		PRESENT ADDRESS
		STREET
DO NOT NOTARIZE UNLESS SIGNED BY SUBJECT (OR PARENT(S) IF UNDER AGE 18) MUST BE SIGNED IN PRESENCE OF NOTARY		CITY STATE ZIP CODE

Exhibit B

COVID-19 Vaccination Record Card

Please keep this record card, which includes medical information about the vaccines you have received.

Por favor, guarde esta tarjeta de registro, que incluye información médica sobre las vacunas que ha recibido.



De Garay [REDACTED] [REDACTED]
Last Name First Name MI

[REDACTED] [REDACTED]
Date of birth Patient number (medical record or IIS record number)

Vaccine	Product Name/Manufacturer	Date	Healthcare Professional or Clinic Site
	Lot Number		
1 st Dose COVID-19	Pfizer-Covid 19 [REDACTED]	12/30/20 mm dd yy	CCHMC
2 nd Dose COVID-19	Pfizer-Covid 19 [REDACTED]	01/20/21 mm dd yy	CCHMC
Other		____/____/____ mm dd yy	
Other		____/____/____ mm dd yy	

gambleprogram@cchmc.org <gambleprogram@cchmc.org>

Mon 5/17/2021 12:27 PM

To: [REDACTED]

Thank you for your request for unblinding.

We are pleased to inform you that you **received the active Pfizer vaccine** as part of the study. Since you have already received the active COVID-19 vaccine, you do not need to receive another COVID-19 vaccine at this time.

Your study visit schedule will remain the same and we look forward to seeing you at your next study visit. If you would like, we will provide you with your COVID-19 vaccine card at your next visit.

Please respond to this email if you have questions or concerns.

Thank you,

Gamble Vaccine Research Center

Cincinnati Children's Hospital Medical Center
The Gamble Program for Clinical Studies
3333 Burnet Avenue, MLC 6014, Cincinnati, OH 45229
Study Line: 513-636-7699 Fax: 513-636-7682
Email: gambleprogram@cchmc.org

Re: Pfizer e-Diary Follow-up #secure

Stephanie de Garay <[REDACTED]>

Thu 6/24/2021 12:35 PM

To: idinformatics <idinformatics@cchmc.org>

[REDACTED] would like to continue with the study, can you please let us know what the activation code is? She has been sick and can't remember what the activation code is.

Thank you

Get [Outlook for iOS](#)

From: idinformatics <idinformatics@cchmc.org>

Sent: Thursday, June 24, 2021 11:58:40 AM

To: [REDACTED] <[REDACTED]>

Subject: Pfizer e-Diary Follow-up #secure

Dear [REDACTED] De Garay,

During a recent review of the electronic diary submissions, our data management team noticed that you have not been entering data into the system. Part of the requirement of the COVID-19 vaccine study in which you are enrolled is completion of electronic diaries. We understand that the electronic diary can be difficult and this has been a reason why some people have chosen to discontinue their participation in the study.

Please respond to this email and let us know whether you will be able to re-start entering data into the electronic system or if you would like us to discontinue your participation in the study. If you choose to not respond to this email, we will assume you have opted to discontinue from the study.

If you have questions or would like to speak to the study team, reply to IDInformatics@cchmc.org and we will connect you with the study team.

Sincerely,

The Pfizer COVID-19 Vaccine Study Data Management Team

Participant Updated Notification Booster



De Garay

Dear Study Families,

Thank you for your continued participation in the Pfizer COVID-19 Vaccine Study.

On Monday, January 3rd, the FDA approved a booster dose of COVID-19 for people 12 years and older who had their 2nd COVID-19 dose at least 5 months ago. The CDC met with their vaccine advisory board on Wednesday, January 5th to review the FDA approval and presented guidelines for a booster dose for 12-15 year olds. Now that these steps have taken place, we can begin to offer booster doses as part of the study.

Over the next couple of weeks, we will be preparing the study materials in order to begin offering booster doses for eligible participants. In the meantime, we have 4 options for you and you can consider:

Option 1: Continue in the current study and receive a 30 mcg booster dose to any age or older as long as it has been at least 6 months since the 2nd dose.

Option 2: Participants ≥ 12 may participate in a sub-study that will evaluate a booster dose of 10 mcg versus a booster dose of 30 mcg. We know that children 5-11 years old given a booster dose of vaccine have the same amount of antibody as 16-25 year olds who get a 30 mcg booster dose. So, we believe a 10 mcg booster in 12-15 olds will produce immunity with less side effects.

Option 3: Participants 12 to 30 years old may participate in a sub-study that looks at developing myocarditis after receiving a 30mcg booster dose.

Option 4: Withdraw from the study and receive a booster dose in the community.

Choice:

* must provide value

- ☐ Option 1: Continue in the current study and receive a booster
- ☐ Option 2 or Option 3: Interested in Sub-studies
- ☐ Option 4: Withdraw from the study and receive a booster dose in the community.
- ☐ No choice: Comment to study team in lieu of choosing an option

Submit

Save & Return Later